AUG 2 6 2005 K 050170

EXHIBIT 12

510(k) SUMMARY

Fortoss Vital™

Applicant

Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person

Mr Simon Fitzer
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Email: sf@biocomposites.com

1.	Classification Name:	Synthetic Bone Graft Material
	Common/Usual Name:	Synthetic Bone Graft Substitute
	Trade/Proprietary Name	Fortoss Vital™ - Bone Graft Substitute
	Product Code	LYC

Legally Marketed Predicate Devices

	Trade Name	Manufacturer	510(k) No
1	Straumann Granules (Bone Graft Substitute)	Straumann AG	K040646
2	Hapset (Bone Graft Material)	Lifecore Biomedical Inc	K910432

Device Description

Fortoss Vital™ Bone Graft Substitute is a calcium phosphate based bone graft substitute and is provided sterile for single patient use. When Fortoss Vital™ is placed in the defect, bone grows in apposition to the implant, filling the pores with new bone during the healing process.

Fortoss Vital™ is completely resorbed and replaced with bone during the healing process.

Intended Use / Indications

Fortoss Vital™ is indicated for placement in osseous defects to provide a mouldable, resorbable graft in periodontal, maxillofacial and dental implant surgery.

Summary of Technology

Fortoss Vital™ is composed of porous calcium salts equivalent to that contained in the predicate devices and to that in routine clinical use. The technologies employed in Fortoss Vital™ and the predicate devices are therefore substantially equivalent. Fortoss Vital™ is presented in granules/powder in the same manner as the predicate devices. The indications, contraindications, risks and potential adverse events are the same and thus substantially equivalent.

Non Clinical Testing

Non clinical testing has been used to examine the chemical composition of Fortoss Vital™ which satisfies the standard for implantable calcium salts.

Clinical Testing

Fortoss Vital™ has been regularly used clinically and no adverse events have been reported in that time concerning the quality, safety or effectiveness of Fortoss Vital™.

Substantial Equivalence

Documentation provided demonstrates that Fortoss Vital™ is substantially equivalent to the legally marketed predicate devices in design, materials and indications.
Fortoss Vital™ is well tolerated and completely incorporated into the defect site into which it is implanted and is safe and effective when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

Biocomposites, Limited.
C/O Mr. Simon Fitzer
Quality and Regulatory Affairs Manager
Keele Science Park
Keel Staffordshire,
UNITED KINGDOM ST5 5NL

Re: K050170/S002
Trade/Device Name: Fortoss Vital Bone Graft Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LPK
Dated: August 5, 2005
Received: August 9, 2005

Dear Mr. Fitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050170

EXHIBIT 1

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Fortoss Vital™

Indications For Use:

Fortoss Vital ™ is intended for placement in osseous defects to provide a mouldable, resorbable graft in periodontal, maxillofacial and dental implant surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter use _____ (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050170